

APR - 6 2004

K023064

510K Notification Supplement
KRD CO., LTD. Hemoclean -K023064[®]
March 29th, 2004

510K(k) SUMMARY

SUBMITTER: KRD CO., LTD.
1529-4 Songjeong-dong, Gangseo-gu,
Busan 618-270, Korea

DATE PREPARED: March 29th 2004

DEVICE NAME: KRD CO., LTD.
HEMOCLEAN[®]

CLASSIFICATION NAMES: System, Dialysate Delivery,
Central and Multiple-
Accessory for Hemodialysis

PREDICATE DEVICE: Minntech/Renal Systems Actril[®]
(510(k) Number: K861730)

Device Description:

HEMOCLEAN[®] is a single component germicide that does not require mixing or activation. HEMOCLEAN[®] is a stabilized mixture of hydrogen peroxide 5.3%(<6.0%) and peracetic acid 1.7%; inert ingredients are 93%. The product is a clear colorless liquid, high acid, and completely soluble in water. HEMOCLEAN[®] finally breaks down to carbon dioxide, water, and oxygen. The product is used full strength with automated dilution by the hemodialysis machine for the intended use. It is packaged in five liters polyethylene containers with a vent filter on the cap and is shipped in two 5-liter containers per box. The shelf life of the concentrate is one year when properly stored.

HEMOCLEAN[®] is indicated for the disinfection of hemodialysis machines. To use HEMOCLEAN[®] in automated hemodialysis machines, the user should follow the manufacture's recommendations for dilution of peracetic acid-based disinfectants. AAMI-quality water for hemodialysis must be used for diluting HEMOCLEAN[®] in the hemodialysis machine.

Predicate Devices:

There has been a device previously cleared by the FDA in the following 510(K) Notification indicated as a disinfectant for hemodialysis machines:

Device	510(k) Document Number	Date Cleared	Indications
Actril [®] Minntech/Renal Systems	K861730	June 9 th , 1987	Artificial Kidney (hemodialysis) Machine Disinfection

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Intended Use:**HEMOCLEAN Indications:**

HEMOCLEAN[®] is intended for the disinfection of artificial kidney machines (hemodialysis machines). It should be used under the following the dilution rate and contact condition:

Hemodialysis Machine	Dilution rate	Contact time
COBE CentrySystem 3	1:9	10 minutes.
Nikkiso DBB 22B	1:34	29 minutes.
Fresenius 2008K	1:34	15 minutes.
Gambro Phoenix	1:25	15 minutes.

Technological Characteristics:

Comparing the proposed devices to the predicate devices, they are substantially equivalent with respect to technological characteristics.

Summary of Non-Clinical Tests:

In vitro performance testing was performed to establish and compare performance characteristics to the predicate devices.

Clinical Test Results:

Testing was performed in a dialysis clinic in hemodialysis machines to demonstrate that the device functioned according to specifications as a hemodialysis machine disinfectant.

Conclusions:

KRD CO., LTD. has performed testing to demonstrate that **HEMOCLEAN[®]** is safe and effective when used according to the instructions for use. Peracetic acid, which is the primary active ingredient in both Actril[®] and **HEMOCLEAN[®]**, has been shown to be an effective biocidal agent. Peracetic acid-based chemical germicides have a long history of use in artificial kidney machines (hemodialysis machines) as disinfection agents. The actions of these germicides are bactericidal, sporicidal, tuberculocidal, pseudomonacidal, virucidal, and are effective against non-tuberculosis mycobacterium (NTM). The decomposition products have low or no toxicity. Efficacy and other performance characteristics are well established by extensive long-term clinical use and well-documented in the scientific literature. The safety and effectiveness performance of **HEMOCLEAN[®]** are identical to the safety and effectiveness performance of Actril[®].



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

KRD Company Limited
C/O Mr. Jeffery R. Shideman
International Medical Products Corporation &
Anderson Consulting International
7307 Gloucester Drive
Edina, Minnesota 55435

Re: K023064

Trade/Device Name: HEMOCLEAN®
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis System and Accessories
Regulatory Class: II
Product Code: NII
Dated: January 8, 2004
Received: January 12, 2004

Dear Mr. Shideman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

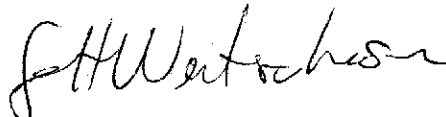
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

for, 
Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): K023064
Device Name: HEMOCLEAN®

INDICATIONS FOR USE:

HEMOCLEAN® Indications:

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Keri M. Kelly for CE
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K023064

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF
NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use
(Optional Format 1-2-96)

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